The GBMC Fertility Center

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December 24, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1061
5360 Fishers Lane
Rockville, Maryland 20852

Re: Docket #97N-484S
Suitability Determination for Donors of Human Cellular and Tissue-Based Products.

Dear Sir/Madam:

I am writing to express my strong disagreement with the proposed rules regarding donor embryos as published in the Federal Register on September 30, 1999. This is based on the lack of evidence that oocytes, embryos or isolated sperm cells used in in vitro fertilization as vectors of the disease listed in the FDA proposal. Furthermore, quarantining embryos will significantly increase the cost and the number of in vitro fertilization cycles necessary to obtain a pregnancy. Patients spend in excess of $15,000 for an in vitro fertilization cycle for pregnancy rates that exceed 50% with fresh cycles. We expect the pregnancy rate to be about half if the embryos have to be frozen. In addition, there will be unnecessary death of embryos from the proposal to mandate freezing.

In summary, given the lack of scientific justification, the increased cost and unnecessary death of embryos, we respectfully request that the rules be revised.

Sincerely,

Eugene Katz

Eugene Katz, M.D.
Director

EK:rjd

97N 484S

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